25, 30, 45-48, and 53-56 are cancelled. All other claims among those originally presented (i.e., original claims 1-56) are fully represented in the current listing provided in the Preliminary Amendment.

37 CFR § 1.121(c)(1)(ii) states that "A marked up version does not have to be supplied for an added claim or a canceled claim as it is sufficient to state that a particular claim has been added, or canceled."

In view of the foregoing, Applicant respectfully submits that the Notice of Non-Compliant Amendment mailed on February 17, 2005 in the above-captioned patent application is in error, and that Applicant's Preliminary Amendment filed on January 23, 2004 is fully compliant and should be entered and considered in the application accordingly.

Respectfully submitted,

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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Lippa et al.

Confirmation No.:

To be assigned

Serial No.:

To be assigned; divisional of U.S.

Application No. 10/425,545

Art Unit:

To be assigned

Filed:

On even date herewith

Examiner:

To be assigned

For:

(-)-1-(3,4-DICHLOROPHENYL)-3-

Attorney Docket No: 10596-017-999

AZABICYCLO[3.1.0]HEXANE, COMPOSITIONS THEREOF, AND

USES AS A DOPAMINE-REUPTAKE INHIBITOR

# PRELIMINARY AMENDMENT UNDER 37 C.F.R. § 1.115

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to Rule 115 of the Rules of Practice, please enter the amendments set forth below and consider the remarks which follow.

Amendments to the specification begin on page 2 of this paper.

Amendments to the claims begin on page 3 of this paper.

Remarks begin on page 7 of this paper.

## Amendments to the specification:

Please insert the following new paragraph after the title on Page 1, paragraph 1:

This application is a divisional of Application No. 10/425,545, filed on April 29, 2003, which is a divisional of Application No. 09/939,071, filed on August 24, 2001, now U.S. Patent No. 6,569,887, dated May 27, 2003.

#### Amendments to the claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

### Listing of claims

Claims 1-23, 25, 30, 45-48 and 53-56 (canceled)

- 24. (original) A method for treating or preventing a disorder alleviated by inhibiting dopamine reuptake, wherein the disorder is selected from the group consisting of attention-deficit disorder, depression, obesity, Parkinson's disease, and a tic disorder, comprising administering to a patient in need of such treatment or prevention an effective amount of (-)-1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane or a pharmaceutically acceptable salt thereof, each being substantially free of its corresponding (+)-enantiomer.
- 26. (original) The method according to claim 24, wherein the attention-deficit disorder is selected from the group consisting of attention-deficit/hyperactivity disorder, predominately inattentive type; attention-deficit/hyperactivity disorder, predominately hyperactivity-impulsive type; attention-deficit/hyperactivity disorder, combined type; conduct disorder; and oppositional defiant disorder.
- 27. (original) The method according to claim 24, wherein the depression is selected from the group consisting of major depressive disorder, recurrent; dysthymic disorder; and major depressive disorder, single episode.
- 28. (original) The method according to claim 24, wherein the Parkinson's disease is neuroleptic-induced parkinsonism.
- 29. (original) The method according to claim 24, wherein the tic disorder is selected from the group consisting of Tourette's disorder, chronic motor disorder, vocal tic disorder, transient tic disorder, stuttering, autistic disorder, and somatization disorder.
- 31. (original) A method for treating or preventing attention-deficit disorder, comprising administering to a patient in need of such treatment or prevention an effective amount of (-)-1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane or a pharmaceutically acceptable salt thereof, each being substantially free of its corresponding (+)-enantiomer.

- 32. (original) The method according to claim 31, wherein the (-)-1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane or pharmaceutically acceptable salt thereof has no more than about 2% w/w of the corresponding (+)-enantiomer.
- 33. (original) The method according to claim 31, wherein the (-)-1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane or pharmaceutically acceptable salt thereof has no more than about 1% w/w of the corresponding (+)-enantiomer.
- 34. (original) The method according to claim 31, wherein the attention-deficit disorder is selected from the group consisting of attention-deficit/hyperactivity disorder, predominately inattentive type; attention-deficit/hyperactivity disorder, predominately hyperactivity-impulsive type; attention-deficit/hyperactivity disorder, combined type; conduct disorder; and oppositional defiant disorder.
- 35. (original) A method for treating or preventing depression, comprising administering to a patient in need of such treatment or prevention an effective amount of (-)-1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane or a pharmaceutically acceptable salt thereof, each being substantially free of its corresponding (+)-enantiomer.
- 36. (original) The method according to claim 35, wherein the (-)-1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane or pharmaceutically acceptable salt thereof has no more than about 2% w/w of the corresponding (+)-enantiomer.
- 37. (original) The method according to claim 35, wherein the (-)-1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane or pharmaceutically acceptable salt thereof has no more than about 1% w/w of the corresponding (+)-enantiomer.
- 38. (original) The method according to claim 35, wherein the depression is selected from the group consisting of major depressive disorder, recurrent; dysthymic disorder; and major depressive disorder, single episode.
- 39. (original) A method for treating or preventing obesity, comprising administering to a patient in need of such treatment or prevention an effective amount of (-)-1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane or a pharmaceutically acceptable salt thereof, each being substantially free of its corresponding (+)-enantiomer.

- 40. (original) The method according to claim 39, wherein the (-)-1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane or pharmaceutically acceptable salt thereof has no more than about 2% w/w of the corresponding (+)-enantiomer.
- 41. (original) The method according to claim 39, wherein the (-)-1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane or pharmaceutically acceptable salt thereof has no more than about 1% w/w of the corresponding (+)-enantiomer.
- 42. (original) A method for treating or preventing Parkinson's disease, comprising administering to a patient in need of such treatment or prevention an effective amount of (-)-1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane or a pharmaceutically acceptable salt thereof, each being substantially free of its corresponding (+)-enantiomer.
- 43. (original) The method according to claim 42, wherein the (-)-1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane or pharmaceutically acceptable salt thereof has no more than about 2% w/w of the corresponding (+)-enantiomer.
- 44. (original) The method according to claim 42, wherein the (-)-1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane or pharmaceutically acceptable salt thereof has no more than about 1% w/w of the corresponding (+)-enantiomer.
- 49. (original) A method for treating or preventing a tic disorder, comprising administering to a patient in need of such treatment or prevention an effective amount of (-)-1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane or a pharmaceutically acceptable salt thereof, each being substantially free of its corresponding (+)-enantiomer.
- 50. (original) The method according to claim 49, wherein the (-)-1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane or pharmaceutically acceptable salt thereof has no more than about 2% w/w of the corresponding (+)-enantiomer.
- 51. (original) The method according to claim 49, wherein the (-)-1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane or pharmaceutically acceptable salt thereof has no more than about 1% w/w of the corresponding (+)-enantiomer.

52. (original) The method according to claim 49, wherein the tic disorder is selected from the group consisting of Tourette's disorder, chronic motor disorder, vocal tic disorder, transient tic disorder, stuttering, autistic disorder, and somatization disorder.

#### **REMARKS**

The specification has been amended to recite the cross-reference to priority applications.

Claims 1-23, 25, 30, 45-48 and 53-56 have been canceled without prejudice.

Applicants reserve the right to pursue the subject matter of the canceled claims in one or more related applications.

No new matter has been added by the amendments made herein.

After entry of the amendments made herein, claims 24, 26-29, 31-44 and 49-52 will be pending in the present application.

## **CONCLUSION**

Applicants respectfully request that the foregoing amendments and remarks be entered and made of record in the file of the instant application.

Pate: January 23, 2004

Respectfully submitted,

January 23, 2004

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Enclosures